QSIT
Validation

The Quality System Inspection Technique (QSIT)

INTRODUCTION

Effective 6/1/97, the Food and Drug Administration (FDA) revised the current Good Manufacturing Practices requirements for medical devices and incorporated them into a Quality System (QS) regulation. With the publication of the QS regulation FDA recognized a total systems approach for regulating medical devices.

The QSIT is a systems type approach to conducting comprehensive inspections of medical device manufacturers.

It was designed and developed by a Center for Devices and Radiological Health (CDRH) sponsored reengineering team, composed of members from CDRH and the Office of Regulatory Affairs, to achieve the following goals and outcomes:

GOALS

G1A **Decrease Time (In-plant):** Decrease the in-plant time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.

G1B **Decrease Time (Total):** Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.

G2A **Increase Focus (FDA 483):** Increase the focus of FDA 483 listed Quality System deficiencies on key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.

G2B **Increase Focus (Inspection Approach)**: Increase the focus of the approach to conducting Quality System inspections on the key elements of the major subsystems of the Quality System with linkages to the remaining subsystems.

G3 **Harmonize:** More closely harmonize the inspection technique for conducting Quality System inspections with that used in the international community.

G4 **QS Regulation Coverage:** Provide broad and adequate coverage of the Quality System regulation when conducting a comprehensive Quality System inspection.

OUTCOMES

O1A **Increase Consistency (Among Districts):** Increase consistency among districts for conducting comprehensive Quality System inspections of medical device manufacturers.

O1B **Increase Consistency (Among Investigators):** Increase consistency among investigators for conducting comprehensive Quality System inspections of medical device manufacturers.

O2 **Increase Compliance:** Increase compliance of medical device manufacturers with the Quality System regulation.

O3 **Improve Product Quality:** Improve the quality of medical devices.

O4 **Improve Review Efficiency:** Improve the efficiency of the enforcement action review process.

Concurrent with the development of the QSIT, activities were designed to validate whether or not the QSIT met these goals and outcomes. These activities were scheduled to take place prior to the full-deployment of the QSIT.

A Table of the Activities including the activity champions and numbers and types of activities associated with the goals and outcomes is below.

QSIT VALIDATION ACTIVITY TABLE

		ACTIVITY	
ITEM	GOAL	TEST (test, inspection, study, demonstration etc.)	ANALYSIS
G1	Decrease Time		
A	In-Plant	Layloff/Wells (1)	
B	Total	Layloff/Wells (1-6)	
G2	Increase Focus		
A	FDA 483	Layloff/Wells (1)	
B	Inspection Approach	Layloff/Wells (1,3)	Ruff (2)
G3	Harmonize	Layloff/Wells (1)	Coleman (2)
G4	QS Reg. Coverage		Ruff (1), AdHoc Group (2)
	OUTCOME:		
O1	Increase Consistency		
A	Among Districts	Layloff/Wells (2,3)	Ruff (1)
B	Among Investigators	Layloff/Wells (2,3)	Ruff (1)
O2	Increase Compliance	Layloff/Wells (1,2)	
O3	Improve Product Quality	Layloff/Wells (1)	
O4	Improve Review Efficiency	Niedelman (1), Layloff/Wells (2)	

A variety of the activities involve data generated under actual use conditions during a QSIT Study. During that Study, inspections of medical device manufacturers were conducted using the QSIT. Study demographics are included in this report.

The QSIT validation activities include input from stakeholders such as investigators, compliance officers, regulated industry and international auditing bodies.

Prior to the conduct of each validation activity, a protocol was developed and documented on a QSIT VALIDATION WORKSHEET. After the conduct of the activity, the results were documented on a QSIT VALIDATION ACTIVITY REPORT.

The documentation associated with the pre-deployment validation activities conducted to date follow this introduction.

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